

## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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	SERIAL NUMBER	FILING DATE		FIRST NAM	MED INVENTOR			TTORNEY DO	CKET NO.	
0	7/845,323	03/03/92	WICK			;	s 43682USA50			
	M OFFICE OF INTELLECTUAL PROP. COUNSEL						EXAMINER HENLEY III,R			
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P.O. BOX 33427						A	RT UNIT	PAPER N	NUMBER	
S	ST. PAUL, I	MN <b>55</b> 133-342	7			<u> </u>	205	6		
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	,		. Parkar	_		DATE N	MAILED.	11/13/9	2	
This is	s a communication from VISSIONER OF PATE	n the examiner in charge of INTS AND TRADEMARKS	your application	A.	•					
	7			•						
	, -		•	•		01-1	a - 11	·		
Z Thi	is application has b	een exemined	Responsiv	re to communi	ication filed on .	8/25/	72 X	This action is m	ade final.	
A short	tened statutory peri	lod for response to this	action is set t	o explre		onth(s),	_	s from the date (	of this letter.	
Fallure	to respond within t	the period for response	will cause the	epplication to	become abanc	doned. 35	U.S.C. 133			
Part I	THE FOLLOW	NG ATTACHMENT(8)	ARE PART O	F THIS ACTIO	)N:		<b>;</b>			
1.		rences Cited by Examin				re Patent Dr			D 150	
3. 6		Cited by Applicant, PTO- How to Effect Drawing		O-1474.	4.   Notice	of Informal F	atent Appil	cation, Form PT(	)- 152. <del>-</del>	
Part II	SUMMARY OF		1 -	_						
1. ,	Claims	-15, 32	nd 3	3			<del></del> .	are pending in t	he applicatio	
	Of the s	above, claims			· · · · · · · · · · · · · · · · · · ·	<u>.=</u>	are	withdrawn from (	consideration	
2.	Ctalms	<u> </u>	<u>_</u>					_ have been can	celled.	
_								_ are allowed.		
3.			_							
4.	Claims	-15,32 a	10 10 10 10 10 10 10 10 10 10 10 10 10 1	<u>.</u>			<u>.</u>	_ are rejected.		
5.	Ctalms							_ are objected t	0.	
	Claims					are subjec	t to restrict	on or election re	quirement.	
<b>U.</b>	-									
7.	This application	on has been filed with in	nformal drawli	ngs under 37 (	C.F.H. 1.85 WNIC	cn are accept	EDIO IOF OX	mination purpos	os.	
8.	Formal drawing	ngs are required in resp	onse to this C	Office action.						
9.	☐ The corrected	or substitute drawings	have been re	celved on			Under 37 C.	F.R. 1.84 these d	irawings	
•	are acce	eptable. not accepte	able (see expl	anation or Not	tice re Patent D	rawing, PTO-	948).			
10.	The proposed	i additional or substitute	e sheet(s) of c	irawings, filed	on	has	(have) been	approved b	y the	
		disapproved by the ex								
11.	☐ The proposed	d drawing correction, file	ed on		., has been 🛚	approved.	disappr	oved (see explan	etion).	
45		nent is made of the claim								
12.		nent is made of the clai d in parent application, :								
13.		plication appears to be					secution as	to the merits is	closed in	
	accordance v	with the practice under I	ex haue ding)	710, 1833 V.U.	11, 400 0.0. 21	· ·				
	C) Other									

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## Claims 1-15, 32 and 33 are presented for examination.

Applicants' amendment and the affidavit of Stephen Berge filed August 25, 1992 have been received and entered into the application. Accordingly, claims 16-31 have been canceled.

Claims 1-15, 32 and 33 remain rejected under 35 U.S.C. § 103 as being unpatentable over Gerster in view of Mahjour et al. and the combination of Kigasawa et al. and Lachman, each of record for the reasons of record as set forth at pages 2-5 of the last Office action dated May 21, 1992.

Applicants' arguments and the Berge affidavit have been given careful consideration but fail to persuade the Examiner of error in his determination of obviousness.

Applicants aver that the affidavit serves to refute the contention that the selection of fatty acids is a matter of choosing from obvious alternatives. The Examiner however, cannot agree.

The affidavit demonstrates results that would have been expected for the use of oleic acid as a penetration enhancer given the explicit disclosure by Mahjour et al. at column 3, lines 11-13.

Respecting the results obtained with isostearic acid, the Examiner will agree that unexpected results are demonstrated in view of Mahjour et al.'s generic teaching of all  $C_{8-24}$  saturated and unsaturated fatty acids as being effective transdermal

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penetration enhances and affiants showing that out of the group of isostearic, stearic and palmitic acids, only isostearic acid provided effective. However, this showing fails to provide a sufficient basis for concluding that the claimed subject matter would have been nonobvious because:

- (1) The results demonstrated pertain to the method in which the ingredients were manipulated rather than to any physical and/or structural characteristics of a composition containing them. Thus, claims 1-15 which delineate compositions are not seen to be patentable.
- (2) Claims 32 and 33 are neither limited to transdermal administration nor to isostearic acid as the penetration enhancer.

For these reasons, it is maintained that applicants' claims 1-15, 32 and 33 are drawn to subject matter that would have been no more than <u>prima facie</u> obvious and are thus properly rejected under 35 USC 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE

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ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Ray Henley whose telephone number is (703) 308-4652.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Pervisory Patent Examiner
Group 120

**HENLEY:** tce

November 10, 1992

RAYMOND J. HENLEY III

PATENT EXAMINER

GROUP 120 - ART UNIT 125